| From the INTERNATIONAL SEARCHING AUTHORITY | PCT |
|--|--|
| To: DORSEY & WHITNEY LLP Attn. Abelev, Gary 250 Park Avenue New York NY 10177 Pat ETATS-UNIS PARENTOUE | NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION ant Mail Received |
| | SEP 0 2 2008 |
| 200 | (PCT Rule 44.1) |
| | Date of mailing |
| | (day/month/year) 27/08/2008 |
| Applicant's or agent's file reference | |
| 189221/PCT | FOR FURTHER ACTION See paragraphs 1 and 4 below |
| International application No. | International filing date |
| PCT/US2008/060600 | (day/month/year) 17/04/2008 |
| Applicant | |
| THE GENERAL HOSPITAL CORPORATION | |
| | The state of the s |
| Authority have been established and are transmitted herew Filing of amendments and statement under Article 18. The applicant is entitled, if he so wishes, to amend the clair When? The time limit for filing such amendments is non international Search Report. Where? Directly to the international Bureau of WIPO_3, 1211 Geneva 20, Switzerland, Fascimile No. (4 For more detailed instructions, see the notes on the ac 2. The applicant is hereby notified that no international search Article 17(2)(a) to that effect and the written opinion of the fr 3. With regard to the protest against payment of (an) addition the protest tocether with the decision thereon has been | ns of the International Application (see Rule 46): mally two months from the date of transmittal of the chemin des Colombettes 11–22) 338.62.70 companying sheet. report will be established and that the declaration under ternational Searching Authority are transmitted herewith. mal fee(s) under Rule 40.2, the applicant is notified that: in transmitted to the International Bureau together with the est and the decision thereon to the designated Offices. idicant will be notified as soon as a decision is made. e international application will be published by the publication, a notice of withdrawal of the International |
| The applicant may submit comments on an informal basis on the informational bursal. This filtermational Bursal auxiliary informational Bursal auxiliary informational bursal auxiliary of international preliminary examination report has been or is to be the public but not before the explication of 30 months from the prior William 19 months from the priority data, but only in respect on examination must be flight the applicant views to examination must be flight the applicant views of the applicant of the submitted of the submitte | written opinion of the international Searching Authority to the such comments to all designated Offices unless established. These comments would also be made available to fitly date. ne designated Offices, a demand for international preliminary introlled the property of the control place until 30 months from the priority ritbin a 20 months from the priority ritbin a 20 months from the priority date, perform the prescribed ces. 1 (or later) will apply even if no demand is filled within 19 licable time limits, Office by Office, see |
| | UOCKETFI |
| Name and mailing address of the International Searching Authority European Patent Office, P.B. 5818 Patentiaan 2 NL_2280 HV Rijswijk Tell. (431–70) 340–3016 Fax: (431–70) 340–3016 | Authorized officer Lars-Oliver Römich |

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the cidians of the international application. It should however be empirisaized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 international process. The process of the p

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume IA, oparagna 296).

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the international Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

FATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

| Applicant's or agent's file reference | FOR FURTHER | |
|---|--|--|
| 189221/PCT | ACTION | see Form PCT/ISA/220 as well as, where applicable, item 5 below. |
| International application No. | International filing date (day/month/y | vear) (Earliest) Priority Date (day/month/year) |
| PCT/US2008/060600 | 17/04/2008 | 17/04/2007 |
| Applicant | | |
| | | |
| THE GENERAL HOSPITAL CORP | ORATION | 7 |
| This international search report has been according to Article 18. A copy is being tr | prepared by this International Searchin ansmitted to the International Bureau. | ng Authority and is transmitted to the applicant |
| This international search report consists | of a total of 6 sheets | |
| | a copy of each prior art document cite | |
| Basis of the report | | |
| With regard to the language, the | international search was carried out or | n the basis of: |
| X the international | application in the language in which it v | was filed |
| a translation of the of a translation fu | e international application into rnished for the purposes of internation | , which is the language al search (Rules 12.3(a) and 23.1(b)) |
| b. This international search authorized by or notified | report has been established taking into to this Authority under Rule 91 (Rule 43 | account the rectification of an obvious mistake |
| | | sclosed in the international application, see Box No. I. |
| 2. X Certain claims were fou | nd unsearchable (See Box No. II) | |
| | | |
| 3. Unity of invention is lac | king (see Box No III) | |
| 4. With regard to the title, | | |
| X the text is approved as su | bmitted by the applicant | |
| the text has been establis | shed by this Authority to read as follows | 3: |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| 5. With regard to the abstract, | | |
| the text is approved as su | | |
| X the text has been establis may, within one month fro | ined, according to Rule 38.2(b), by this om the date of mailing of this internation | Authority as it appears in Box No. IV. The applicant nal search report, submit comments to this Authority |
| With regard to the drawings. | | |
| | ublished with the abstract is Figure No | . 1 |
| X as suggested by | * | • |
| | s Authority, because the applicant faile | ad to europeet a figure |
| | s Authority, because the applicant falle s Authority, because this figure better of | |
| | s Authority, because this rigure better o e published with the abstract | priditaciones ine invention |
| I mone or the rightes is to b | o passionou with the abstract | - |

INTERNATIONAL SEARCH REPORT

international application No.

PCT/US2008/060600

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

An apparatus and method for providing imaging information associated with at least one portion of a sample, such as an ear. For example, at least two first different wavelengths of at least one first electro-magnetic radiation within a first wavelength range may be provided on the portion of the sample so as to determine at least one first transverse location of the portion. At least two second different wavelengths of at least one second electro-magnetic radiation may also be provided within a second wavelength range provided on the portion so as to determine at least one second transverse location of the portion. It is possible to obtain a relative phase between at least one third electro-magnetic radiation elec

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B1/227 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols) A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, BIOSIS, COMPENDEX, WPI Data

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|-----------------------|
| X | DATABASE COMPENDEX [Online] ENGINEERING INFORMATION, INC., NEW YORK, NY, US; 5 March 2007 (2007-03-05), YELIN DVIR ET AL: "Spectral-domain spectrally-encoded endoscopy" XP002492321 Database accession no. E20071110483178 See: "I.Introduction" page 2432; "3.Result", in particular page 2441, last paragraph; figures 1 and 10. & OPT. EXPRESS; OPTICS EXPRESS MAR 5 2007. | * 1-11 |
| | vol. 15, no. 5, 5 March 2007 (2007-03-05), pages 2432-2444,/ | ** |

| ١ | 🗠 | ٠. | | | | |
|---|---|----|------|------|----------|--|
| 1 | | | | -141 | al conse | |

- "A" document defining the general state of the art which is not
- considered to be of particular relevance "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or
- other means 'P' document published prior to the international filing date but later than the priority date claimed
- Date of the actual completion of the international search

- *T* later document published after the international filling date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family Date of mailing of the international search report

27/08/2008

Authorized officer

15 August 2008 Name and mailing address of the ISA/

Dhervé, Gwenaëlle

European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl. Fax: (+31-70) 340-3016

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT Category* Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No. X WO 2006/130797 A (GEN HOSPITAL CORP [US]: 1-11BOUMA BRETT EUGENE [US]; TEARNEY GUILLERMO (J [) 7 December 2006 (2006-12-07) abstract χ WO 02/38040 A (GEN HOSPITAL CORP [US]; 1-11TEARNEY GUILLERMO J [US]; BOUMA BRETT EUGENE [) 16 May 2002 (2002-05-16) page 7, line 5 - page 8, line 17; figure 1 page 16, line 16 - page 21, line 11 χ DATABASE BIOSIS [Online] 1-11BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; October 2006 (2006-10), YELIN D ET AL: "Three-dimensional miniature endoscopy" XP002492322 Database accession no: PREV200700043625 the whole document & NATURE (LONDON), vol. 443, no. 7113. October 2006 (2006-10), page 765, ISSN: 0028-0836 WO 79/00841 A (NAT RES DEV [GB]; PETTIGREW 1 - 11A [AU]; ANSON M [GB]; CHUNG S [GB]) 18 October 1979 (1979-10-18) abstract US 4 834 111 A (KHANNA S M [US] ET AL) 1 - 1130 May 1989 (1989-05-30) column 1, line 1 - column 2, line 51

INTERNATIONAL SEARCH REPORT

| Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet) | |
|--|---|
| This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons: | |
| Claims Nos.: 12-21 because they relate to subject matter not required to be searched by this Authority, namely: | |
| Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery | 0 |
| Claims Nos.: because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically: | |
| | |
| Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a). | |
| Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet) | |
| This International Searching Authority found multiple inventions in this international application, as follows: | _ |
| | |
| | |
| | |
| | |
| As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims. | |
| As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees. | |
| | |
| 3. As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers | |
| only those claims for which fees were paid, specifically claims Nos.: | ~ |
| | |
| | |
| | |
| No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: | |
| | |
| Remark on Protest The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee. | |
| The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation. | |
| No protest accompanied the payment of additional search fees. | |

information on patent family members

ii ational application No PCT/US2008/060600

| | atent document d in search report | | Publication date | | Patent family member(s) | | Publication date |
|----|--------------------------------------|---|------------------|----------------------|--|---------|--|
| WO | 2006130797 | Α | 07-12-2006 | EP US | 1887926 2006270929 | | 20-02-2008 30-11-2006 |
| WO | 0238040 | Α | 16-05-2002 | AU EP US | 3119802 1343411 2008013960 | A2 | 21-05-2002 17-09-2003 17-01-2008 |
| WO | 7900841 | A | 18-10-1979 | DE EP GB US | 2964775 0014705 2047894 4339954 | A1 A | 24-03-1983 03-09-1980 03-12-1980 20-07-1982 |
| US | 4834111 | Α | 30-05-1989 | NONE | - 1 | | |

ATENT COOPERATION TRL .TY

From the INTERNATIONAL SEARCHING AUTHORITY PCT To WRITTEN OPINION OF THE see form PCT/ISA/220 INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1) Date of mailing (day/month/year) see form PCT/ISA/210 (second sheet) Applicant's or agent's file reference FOR FURTHER ACTION see form PCT/ISA/220 See paragraph 2 below International application No. International filing date (day/month/year) Priority date (day/month/year) PCT/US2008/060600 17.04.2008 17.04.2007 International Patent Classification (IPC) or both national classification and IPC INV. A61B1/227 A61B5/00 Applicant THE GENERAL HOSPITAL CORPORATION This opinion contains indications relating to the following items: Box No. I Basis of the opinion ☐ Box No. II Priority Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability ☐ Box No. IV Lack of unity of invention □ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement ☐ Box No. VI Certain documents cited Box No. VII Certain defects in the international application ☐ Box No. VIII Certain observations on the international application FURTHER ACTION If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered. If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later. For further options, see Form PCT/ISA/220. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:

Date of completion of this opinion Authorized Officer

<u>a</u>))

European Patent Office - P.B. 5818 Patentla age form NL-2280 HV Rijswijk - Pays Bas Tel. 431 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016

Dhervé, Gwenaëlle



| The state of the s | | |
|--|--|-----|
| Box No. I Basis of the opinion | | |
| 1. With regard to the language, this opinion has been established on the ba | asis of: | |
| ☐ the international application in the language in which it was filed | | |
| a translation of the international application into , which is the langua purposes of international search (Rules 12.3(a) and 23.1 (b)). | age of a translation furnished for the | |
| 2. This opinion has been established taking into account the rectification by or notified to this Authority under Rule 91 (Rule 43bis.1(a)) | on of an obvious mistake authorize | ∍d |
| With regard to any nucleotide and/or amino acid sequence disclosed in necessary to the claimed invention, this opinion has been established on | | |
| a. type of material: | | |
| ☐ a sequence listing | | |
| ☐ table(s) related to the sequence listing | | |
| b. format of material: | | |
| □ on paper | | |
| in electronic form. | | |
| c. time of filling/furnishing: | | • |
| ☐ contained in the international application as filed. | | |
| ☐ filed together with the international application in electronic form. | | |
| ☐ furnished subsequently to this Authority for the purposes of search | h. | |
| 4. \[\begin{array}{l} \begin{array}{l} In addition, in the case that more than one version or copy of a seque has been filed or furnished, the required statements that the informat copies is dentical to that in the application as filed or does not go bey appropriate, were furnished. \] | tion in the subsequent or additional | ėto |
| 5. Additional comments: | | |

| | x No. III Non-establishment of opinion with regard to novelty, inventive step and industrial plicability |
|-------------|--|
| | e questions whether the claimed invention appears to be novel, to involve an inventive step (to be non vious), or to be industrially applicable have not been examined in respect of |
| \boxtimes | the entire international application |
| | claims Nos. |
| bed | cause: |
| ⊠ | the said international application, or the said claims Nos. 12-21 relate to the following subject matter which does not require an international search (specify): |
| | see separate sheet |
| ⊠ | the description, claims or drawings (indicate particular elements below) or said claims Nos. 1-21 are so unclear that no meaningful opinion could be formed (specify): |
| | see separate sheet |
| ⊠ | the claims, or said claims Nos. $\underline{1\cdot21}$ are so inadequately supported by the description that no meaningful opinion could be formed ($specify$): |
| | see separate sheet |
| \boxtimes | no international search report has been established for the whole application or for said claims Nos |
| | a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit: |
| | ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it. |
| | ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it. |
| | □ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13 ter.1(a) or (b). |
| | a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it. |
| | the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions. |
| | See Supplemental Box for further details |
| | |

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/US2008/060600

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

III.1. No meaningful opinion can be formed with regard to novelty, inventive step and industrial applicability of **claims 1-11** (Article 34(4)(a)(ii) PCT/Article 35(3)(a) PCT) because of lacks of clarity (Article 6 PCT) and insufficient disclosure (Article 5 PCT) as explained below.

First of all, the independent claim 1 refers to arrangements, at least one arrangement being configured to provide at least one first and one second EM radiation so as to determine at least one first and one second location of a portion of a sample, at least another arrangement configured to obtain a relative phase between at least one third and one fourth radiation to determine a motion, and at least one third arrangement configured to provide imaging information based on said first transverse location, said second transverse location and said motion.

However, the description does not <u>describe</u> (emphasis added) such a combination of features. At the most, it is made reference in the description to the use of a SEE probe in the system but without indication with respect the technical features which are needed for the system to provide imaging information as claimed in claim 1, in particular information relating to the motion. Moreover, the apparatus shown on figure 1 of the present application (see also paragraphs [0016] and [0017]) and identified as "an exemplary embodiment of an apparatus for measuring motion with SEE according to the present invention", is not disclosed as comprising more or other features than those of the three-dimensional spectrally encoded imaging apparatus disclosed in the applicant's prior application WO-A-2006/130797.

Hence, the description does not disclose the claimed invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art as required by Article 5 PCT (see also the PCT Guidelines, 4.02, 4.10 and 4.13).

Furthermore, the wording of the independent claim 1, as such, is rendered unclear because of the repetitive use of undefined/broad terms ("at least one...", "first/second/third arrangements"), the broad meaning of those terms being not commensurate with the

limited description of the invention.

The vague and imprecise statement in the description on page 4, paragraph [0015] and on page 6, paragraph [0020], especially the mention to "the spirit of the invention", and the fact that the subject-matter of the independent claim 1 is presented in the description as "exemplary embodiment of the present invention" (see paragraphs [0005] and [0006]), implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in a further lack of clarity of the claims (see also the PCT Guidelines, 5.29 and 5.30).

The dependent claims 2, 6, 7 and 8 further define features of <u>a sound wave which do not limit the scope the invention</u> since the apparatus defined in claim 1 does not comprise the device for providing a sound wave.

Finally, it is not clear in which extent the <u>anatomical references</u> defined in the dependent claims 3, 4 and 10 should imply structural limitations to the claimed apparatus as such. The aforementioned claims therefore lack clarity and are not supported by the description contrary to the requirements of Article 6 PCT.

III.2. No examination is carried out on claims 12-21 because they relate to a "method for providing imaging information" which involves a treatment of the living body by surgery. Indeed, as described in the description (see, in particular, paragraph [0017]), the method implies the step of inserted a SEE probe through an incision in the tympanic membrane. Such an invasive method is covered by the provision of Rule 67(1)(iv) PCT (see also the PCT Guidelines, 9.08-9.10 and Rule 43bis.1(b) PCT)

The attention of the applicant's is further drawn to the fact that those claims also infringe the requirements of Articles 5 and 6 PCT for reasons similar to those given above with respect to the apparatus-claims.

Re Item VII

Certain defects in the international application

VII.1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents WO-A-2006/130797 and XP002492321 (YELIN DVIR ET AL: "Spectral-domain spectrally-encoded endoscopy"; 5 March 2007) is not mentioned in the

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (SEPARATE SHEET)

International application No.

PCT/US2008/060600

description, nor are these documents identified therein.

VII.2. The mention "incorporated herein by reference" on page 6, paragraph [0020] should be deleted. If the referred to documents are useful for understanding the claimed invention, a brief summary of their content should be included in the description (see the PCT Guidelines, 4.26).

Possible steps after receipt of the international search report (ISR) and written opinion of the International Searching Authority (WO-ISA)

General information

For all international applications filed on or after 01/01/2004 the competent ISA will establish an ISR. It is accompanied by the WO-ISA. Unlike the former written opinion of the IPEA (Rule 66.2 PCT), the WO-ISA is not meant to be responded to, but to be taken into consideration for further procedural steps. This document explains about the possibilities.

under Art. 19 PCT

Amending claims Within 2 months after the date of mailing of the ISR and the WO-ISA the applicant may file amended claims under Art. 19 PCT directly with the International Bureau of WIPO. The PCT reform of 2004 did not change this procedure. For further information please see Rule 46 PCT as well as form PCT/ISA/220 and the corresponding Notes to form PCT/ISA/220.

Filing a demand for international preliminary examination

In principle, the WO-ISA will be considered as the written opinion of the IPEA. This should, in many cases, make it unnecessary to file a demand for international preliminary examination. If the applicant nevertheless wishes to file a demand this must be done before expiry of 3 months after the date of mailing of the ISR/WO-ISA or 22 months after priority date, whichever expires later (Rule 54bis PCT), Amendments under Art. 34 PCT can be filed with the IPEA as before, normally at the same time as filing the demand (Rule 66.1 (b) PCT).

If a demand for international preliminary examination is filed and no comments/amendments have been received the WO-ISA will be transformed by the IPEA into an IPRP (International Preliminary Report on Patentability) which would merely reflect the content of the WO-ISA. The demand can still be withdrawn (Art. 37 PCT).

Filing informal comments

After receipt of the ISR/WO-ISA the applicant may file informal comments on the WO-ISA directly with the International Bureau of WIPO. These will be communicated to the designated Offices together with the IPRP (International Preliminary Report on Patentability) at 30 months from the priority date. Please also refer to the next box.

End of the international phase

At the end of the international phase the International Bureau of WIPO will transform the WO-ISA or, if a demand was filed, the written opinion of the IPEA into the IPRP, which will then be transmitted together with possible informal comments to the designated Offices. The IPRP replaces the former IPER (international preliminary examination report).

Relevant PCT Rules and more information

Rule 43 PCT, Rule 43bis PCT, Rule 44 PCT, Rule 44bis PCT, PCT Newsletter 12/2003, OJ 11/2003, OJ 12/2003

Bitte beachten Sie, dass angeführte Nichtpatentliteratur (wie z.B. wissenschaftliche oder technische Dokumente) je nach geltendem Recht dem Urheberrechtsschutz und/oder anderen Schutzarten für schriftliche Werke unterliegen könnte. Die Vervielfältigung urheberrechtlich geschützter Texte, ihre Verwendung in anderen elektronischen oder gedruckten Publikationen und ihre Weitergabe an Dritte ist ohne ausdrückliche Zustimmung des Rechtsinhabers nicht gestattet.

Veuillez noter que les ouvrages de la littérature non-brevets qui sont cités, par exemple les documents scientifiques ou techniques, etc., peuvent être protégés par des droits d'auteur et/ou toute autre protection des écrits prévue par les législations applicables. Les textes ainsi protégés ne peuvent être reproduits ni utilisés dans d'autres publications électroniques ou imprimées, ni rediffusés sans l'autorisation expresse du titulaire du droit d'auteur.

Please be aware that cited works of non-patent literature such as scientific or technical documents or the like may be subject to copyright protection and/or any other protection of written works as appropriate based on applicable laws. Copyrighted texts may not be copied or used in other electronic or printed publications or re-distributed without the express permission of the copyright holder.

ITENT COOPERATION TREATY

| From the INTERNATIONAL SEARCHING AUTHORITY | | PCT | | | | |
|--|--|--|---|--|--|--|
| To: | | | 101 | | | |
| DORSEY & WHITNEY LLP | | | DTIFICATION OF RECEIPT | | | |
| Attn. Abelev, Gary | 9 | Patent Mail R | eCeive: | | | |
| 250 Park Avenue New York NY 10177 | | 1 HIM O 4 00 | 100 (COT D) 25 (1) | | | |
| BTATS-UNIS D'AMERIQUE | ı | JUN 0 4 ZI | (PCT Rule 25.1) | | | |
| DITTO GALD D MAINTAGOD | | | | | | |
| - | | | | | | |
| | | Date of mailing | | | | |
| | | (day/month/year) | 22/05/2008 | | | |
| Applicant's or agent's file reference | | | 22/05/2008 | | | |
| | | · IM | PORTANT NOTIFICATION | | | |
| 189221/PCT | T | L | | | | |
| International application No. | International filing date(| | Priority date (day/month/year) | | | |
| PCT/US2008/060600 |]3 | 17/04/2008 | 17/04/2007 | | | |
| Applicant | | | | | | |
| THE GENERAL HOSPITAL CORPO | DA MTON | | | | | |
| THE GENERAL HOSPITAL CORPO | RATION | | | | | |
| | | | | | | |
| Where the International Searching | | | | | | |
| Authority on the date indicated below | ne search copy of the inte | r national application | vas received by this International Searching | | | |
| | | | • | | | |
| Where the leteraction of Countries | A | | | | | |
| Where the International Searching | | | | | | |
| The applicant is hereby notified that ti | ne search copy of the inter | rnational application w | as received on the date indicated below. | | | |
| | | | | | | |
| 02/05/2008 (date of receipt). | | | | | | |
| | | | | | | |
| 2. The search copy was accompanied by a nucleotide and/or amino acid sequence listing or tables related thereto in | | | | | | |
| The search copy was accompanied by a nucleotide and/or amino acid sequence listing or tables related thereto in electronic form. | | | | | | |
| | | | | | | |
| 3. The search convicontained a nuc | 3. The search copy contained a nucleotide and/or amino acid sequence listing or tables related thereto in electronic form. | | | | | |
| | noondo andror armiro acid | sequence liating or ta | bies related thereto in electronic form. | | | |
| | | | | | | |
| Time limit for establishment of inter | mational search report a | and written opinion o | f the International Searching Authority | | | |
| The applicant is informed that the time International Searching Authority is the | limit for establishing the i | international search re of receint indicated ab | port and the written opinion of the ove or nine months from the priority date, | | | |
| whichever time limit expires later (Rule | 3s 42.1 and 43bis.1(a)) | or roompt manation and | ove or raine months from the priority date, | | | |
| | | | | | | |
| 5 A conv of this notification has been se | nt to the International Burn | one and whore the fire | at contains of several to a line | | | |
| A copy of this notification has been sent to the International Bureau and, where the first sentence of paragraph 1 applies, to the receiving Office. | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | l | | | |
| | | | | | | |
| | | | | | | |
| Name and mailing address of the International | | Authorized officer | | | | |
| European Patent Office, P.B. 58 NL-2280 HV Rijswijk | 18 Patentiaan 2 | | TGA /BD | | | |
| Tel. (+31-70) 340-2040, Tx. 31 6 | 51 epo ni, | | ISA/EP | | | |
| Fax: (+31-70) 340-3016 | i | | | | | |

Form PCT/ISA/202 (April 2005)